

Remarks/Argument

Applicant have received and carefully reviewed the Office Action mailed on April 26, 2011. Claims 43, 44, 46, 49, 52, and 64 have been rejected. With this Amendment, claims 52, 67, and 69-73 have been amended and claims 65 and 66 have been canceled without prejudice. Claims 43, 44, 46, 49, 52, 59-64, and 67-73 remain pending. Favorable consideration of the following remarks is respectfully requested.

Allowable Subject Matter

Applicants thank the Examiner for indicating that claims 66-68 and 70-73 would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Independent claim 52 has been amended to include the limitations of claim 66, thus claim 52 and the claims dependent thereon are believed to be allowable.

Claim Rejections - 35 U.S.C. § 103

On page 2 of the Office Action, claims 43, 44, 46, and 49 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Lane et al. (U.S. Patent No. 7,527,622) in view of Danek et al. (U.S. Publication No. 2002/0091379). Applicant respectfully traverses the rejection.

Turning to claim 43, which recites:

43. (Previously Presented) A device for minimally invasive medical treatment in a body of a patient, comprising:
- a tubular member having a proximal end and a distal end;
 - a cryo therapy apparatus connected to the distal end of the tubular member, wherein the cryo therapy apparatus comprises a first balloon and a second balloon, the first and second balloons arranged to define an inner chamber and an outer chamber, at least a portion of the inner chamber being interior of the first balloon and at least a portion of the outer chamber being interior of the second balloon and exterior of the first balloon, a surface of the first balloon configured to retain a coolant within the inner chamber and a surface of the second balloon configured to retain the coolant within the cryo therapy apparatus if the first balloon fails; and

an optical sensor disposed within the cryo therapy apparatus for monitoring temperatures created by use of the cryo therapy apparatus from within the cryo therapy apparatus, the optical sensor coupled to a retractable member capable of moving independently of the cryo therapy apparatus;
wherein the cryo therapy apparatus is sized and arranged for vascular introduction.

Nothing in Lane et al. or Danek et al., taken either alone or in combination, appear to disclose many elements of claim 43, including for example, “an optical sensor disposed within the cryo therapy apparatus for monitoring temperatures created by use of the cryo therapy apparatus from within the cryo therapy apparatus, the optical sensor coupled to a retractable member capable of moving independently of the cryo therapy apparatus”.

In the Office Action, the Examiner appears to indicate that Lane et al. fails to disclose the claimed optical sensor, but turns to Danek et al. for support. In particular, the Examiner cites to paragraph 37 of Danek et al. and states “Danek et al. disclose a catheter with an on-board optical temperature sensor which meets all of the limitations not disclosed by Lane et al.” Applicants respectfully disagree. The cited passages of Danek et al. states:

[0037] The energy delivery device may further comprise a temperature detecting element. Examples of temperature detecting elements include thermocouples, infrared sensors, thermistors, resistance temperature detectors (RTDs), or any other apparatus capable of detecting temperatures or changes in temperature. The temperature detecting element is preferably placed in proximity to the expandable member.

However, nowhere does the cited passage of Danek et al. appear to teach, suggest, or disclose a temperature sensing element disposed within the energy delivery device for monitoring temperatures created by use of the energy delivery device from within the energy delivery device, or the temperature detecting element coupled to a retractable member capable of moving independently of the energy delivery device. Hence, the cited passage cannot be considered as teaching, suggesting, disclosing “an optical sensor disposed within the cryo therapy apparatus for monitoring temperatures created by use of the cryo therapy apparatus from within the cryo therapy apparatus, the optical sensor coupled to a retractable member capable of moving independently of the cryo therapy apparatus”, as recited in claim 43. On page 3 of the Office Action, the Examiner asserts that “the requirement that the optical sensor

is coupled to a retractable member capable of moving independently of the cryo therapy apparatus is considered by the examiner to be merely an obvious engineering design choice well known to one of ordinary skill in the art and that placing of multiple temperature sensors along the interior of the inner balloon would be an obvious alternative equivalent because the movement of the optical sensor as claimed would not provide any unexpected results.” Applicants respectfully disagree. The Examiner appears to have acknowledged that neither Lane et al. nor Danek et al. teach an optical sensor coupled to a retractable member as recited in claim 43. The Examiner appears to be asserting that the modification necessary to achieve the claimed structure is an obvious design choice. Applicants respectfully disagree. The claimed structure is not a mere design element but instead provides a particular function based on the claimed structure. Additionally, Danek et al. do not appear to teach an optical sensor disposed within the cryo therapy apparatus, let alone being disposed on a retractable member. As can be seen in the quote above, Danek et al. merely teach a temperature detecting element “placed in proximity to the expandable member.” There is nothing in Danek et al. to suggest placing a temperature detecting element within the expandable member, or on a retractable member, as recited in the claims. The only reason for one of ordinary skill in the art to modify Lane and Danek to achieve the claimed structure is based on Applicants’ specification, which is an error.

The Supreme Court in *KSR Int’l Co. v. Teleflex Inc.* quotes *In re Kahn*, 441 F. 3d 977, 988 (CA Fed. 2006) stated:

“[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness”.

Emphasis added; see page 14 of the April 30, 2007 decision. The Examiner has not provided any articulated reasoning with rational underpinning to support the conclusion of obviousness. The Examiner appears to be asserting that one could modify Land and Danek to achieve the claimed structure, which is clearly an improper ground for obviousness. The Court in *KSR* further stated:

a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art.

See page 14 of the April 30, 2007 decision. The Examiner has not provided any objective reason to modify Lane and Danek in the manner recited in claim 43, other than relying on the instant specification, which is clear error.

Accordingly, there appears to be no reason to modify Lane et al. and Danek et al. to have an optical sensor disposed within the cryo therapy apparatus for monitoring temperatures created by use of the cryo therapy apparatus from within the cryo therapy apparatus, the optical sensor coupled to a retractable member capable of moving independently of the cryo therapy apparatus. For at least these reasons, claim 43 is believed to be patentable over Lane et al. in view of Danek et al. For similar and other reasons, claims 44, 46, and 49, which depend from claim 43 and include additional distinguishing features, are also believed to be patentable over Lane et al. in view of Danek et al. Withdrawal of the rejection is respectfully requested.

On page 4 of the Office Action, claims 52, 64, 65, and 69 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Lane et al. in view of LePivert (U.S. Patent No. 6,551,309). Applicant respectfully traverses the rejection. However, in the interest of advancing prosecution, independent claim 52 has been amended to recite elements of claim 66, which was indicated as being allowable. As such, Applicants submit that independent claim 52, and dependent claims 64 and 69 are allowable over the prior art.

Conclusion

In view of the foregoing, all pending claims are believed to be in a condition for allowance. Further examination and withdrawal of the rejections is respectfully requested. Issuance of a Notice of Allowance in due course is anticipated. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,
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By his Attorney,

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